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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------|------------------------------|----------------------|-------------------------|------------------|
| 10/517,032 | 12/07/2004 | Sergio Capurro | BA-22902 | 2851 |
| 178 BUCKNAM A | 7590 03/19/2007 ND ARCHER | | EXAMINER YABUT, DIANE D | |
| | ERN BOULEVARD | | | |
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| | | | 3734 | |
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| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | Application No. | Applicant(s) | \$b | | | |
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| Office Action Summary | | | | • | | | |
| | | 10/517,032 | CAPURRO, SERGIO | | | | |
| | Onice Action Cummary | Examiner | Art Unit | | | | |
| - | The MAILING DATE of this communication a | Diane Yabut | vith the correspondence address | | | | |
| Period fo | | ppears on the cover sheet v | nui die correspondence address | | | | |
| WHIC - Exte after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REP CHEVER IS LONGER, FROM THE MAILING nsions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory perior re to reply within the set or extended period for reply will, by stat reply received by the Office later than three months after the mai ed patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUN 1.136(a). In no event, however, may a nd will apply and will expire SIX (6) MO ute, cause the application to become A | ICATION. reply be timely filed NTHS from the mailing date of this communicati BANDONED (35 U.S.C. § 133). | • | | | |
| Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 26 | December 2006. | | | | | |
| • — | This action is FINAL. 2b) This action is non-final. | | | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| | closed in accordance with the practice under | r Ex parte Quayle, 1935 C. | D. 11, 453 O.G. 213. | | | | |
| Disposit | ion of Claims | | | | | | |
| 5)□ 6)⊠ 7)□ | Claim(s) <u>1-13</u> is/are pending in the application 4a) Of the above claim(s) is/are withded Claim(s) is/are allowed. Claim(s) <u>1-13</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and | rawn from consideration. | | | | | |
| Applicat | ion Papers | | | | | | |
| 10)⊠ | The specification is objected to by the Exami The drawing(s) filed on <u>07 December 2004</u> is Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the | s/are: a)⊠ accepted or b)[ne drawing(s) be held in abeya ection is required if the drawin | ance. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1.121 | | | | |
| , | under 35 U.S.C. § 119 | | | | | | |
| 12) <u>□</u> a) | Acknowledgment is made of a claim for forei All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure See the attached detailed Office action for a light | ents have been received. ents have been received in riority documents have bee eau (PCT Rule 17.2(a)). | Application No n received in this National Stage | · | | | |
| 2) Noti | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date | Paper No | Summary (PTO-413) o(s)/Mail Date Informal Patent Application | | | | |

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DETAILED ACTION

This action is in response to applicant's amendment received on 26 December 2006.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scirica et al.** (U.S. Patent No. **5,908,428**) in view of **Munoz** (U.S. Patent No. **5,792,180**).

Claim 1: Scirica et al. discloses a needle having two tips with a central portion equipped with a hole 212 through which emerges a surgical thread 34 that is anchored inside the needle (Figure 7 and col. 10, lines 21-26). Scirica et al. discloses the claimed device except for the needle being atraumatic and consisting of a tubular metal shaft.

Munoz teaches high strength atraumatic needles consisting of a tubular metal shaft (Figure 6, col. 5, lines 1-3). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an atraumatic, tubular metal shaft, as taught by Munoz, to Scirica et al since it was known in the art that atraumatic, tubular metal shaft needles are commonly used in surgery to reduce the damage of punctured tissue of a patient.

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Claim 2: Scirica et al. discloses a needle wherein its tips are beveled two oblique planes and the hole **212** through which the thread **34** passes involves only one wall of the hollow shaft (Figure 7).

Claim 3: Scirica et al. discloses a needle wherein one end of the surgical thread **34** is inserted into the hole **212** of the needle and is anchored by pinching the needle (Figure 7 and col. 10, lines 21-26).

3. Claims 4-6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scirica et al.** (U.S. Patent No. **5,908,428**) and **Munoz** (U.S. Patent No. **5,792,180**), as applied to Claim 1 above, and further in view of **Flagg et al.** (U.S. Patent No. **2,240,330**).

Claims 4-6: Scirica et al. discloses the claimed device, including a surgical thread being inserted into the hole of an atraumatic two-tipped needle, in combination with Munoz, except for being made to emerge from one end, the surgical thread being equipped with a knot and adapted to be drawn back inside the shaft towards the hole or be equipped with a knot in advance, being inserted into one end of the needle.

Flagg et al. teaches a surgical thread being equipped with a knot **13** emerging from one end and being adapted to be drawn back inside the shaft towards the hole or be equipped with a knot in advance or to be inserted into one end of the needle and emerged through the hole, in order to secure a suture to a needle hole (Figure 12, col. 2, lines 52-54). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a knot for anchoring the surgical thread, as taught by Flagg et al.,

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to the combined device of Scirica et al. and Munoz, since it was known in the art that the use of knots to anchor threads to surgical needles and other fields of endeavor to limit the movement of a suture, thread, or cord through an opening using a knot is commonly used.

Claim 13: Scirica et al. and Munoz disclose the claimed device except for the surgical thread being fixed by means of two or more anchoring techniques

Flagg et al. teaches a surgical thread being fixed by means of two or more anchoring techniques to ensure a firm grip on the suture (col. 5, lines 3-8). It would have been obvious to one of ordinary skill in the art to provide a thead being fixed by means of two or more anchoring techniques, as taught by Flagg et al., to the combined device of Scirica et al. and Munoz, in order to ensure a firm anchoring grip on the suture.

4. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Scirica et al. (U.S. Patent No. 5,908,428) and Munoz (U.S. Patent No. 5,792,180), as applied to Claim 1 above, and further in view of Coplan (U.S. Patent No. 3,918,455).

Claims 7-11: Scirica et al. discloses the claimed device, including an atraumatic surgical needle with one end of the surgical thread being inserted into the hole and being anchored inside the atraumatic two-tipped needle by pinching, in combination with Munoz, except for being anchored by means of a scotch, a solid bar or a portion of tube, made of metal or plastic, the caliber of which is determined by the diameter of the needle, which is pushed down inside the needle from one of the two ends.

Coplan teaches a surgical thread, emerging from one end of the needle, being inserted and anchored, or fixed, in a hole in one end of a scotch **34**, a solid bar or a portion of tube, made of metal or plastic, the caliber of which is determined by the diameter of the needle, which is pushed down inside the needle from one of the two ends (Figure 4, col. 4, lines 55-63 and col. 6, lines 60-62). Coplan teaches that the use of the scotch **34** for a suture-needle combination reduces trauma at the site of tissue penetration and reduces hazard of suture tear-out (col. 1, lines 60-68). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device disclosed by Scirica and Munoz to provide a scotch, which is pushed down inside the needle from one of two ends, as taught by Coplan, in order to reduce trauma at the site of tissue penetration and hazard of suture tear-out.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scirica** et al. (U.S. Patent No. **5,908,428**) and **Munoz** (U.S. Patent No. **5,792,180**), as applied to Claim 1 above, and further in view of **Borst et al.** (U.S. Pub. No. **20040260145**).

Claim 12: Scirica et al. and Munoz disclose the claimed device, including a surgical thread being inserted into an atraumatic two-tipped needle, except the thread being fixed between the coils of a tiny spring.

Borst et al. teaches a suture being fixed between the coils of a tiny spring (page 11, paragraph 132). It would have been obvious to one of ordinary skill in the art to fix a suture between the coils of a tiny spring, as taught by Borst et al., to the combined

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device of Scirica et al. and Munoz since it was known in the art that springs are used as flexible retaining means for sutures, threads, and cords.

Response to Arguments

- 6. Applicant's arguments filed 26 December 2006 have been fully considered but they are not persuasive.
- 7. The applicant argues that neither Scirica et al. nor Munoz teaches an atraumatic needle, which is defined as not having an eye for passage of thread causing less trauma to tissue because of the lack of the eye and the double thread passing through the eye. The examiner disagrees. The needle of Scirica et al. is modified using the reference of Munoz whose needle is disclosed as atraumatic, as maintained above (Figure 6, col. 5, lines 1-3) in that a high strength metal needle imposes less trauma on tissue, hence it is "atraumatic." If using the applicant's definition of atraumatic, the needle of Scirica et al. apparently reads on the limitation of an atraumatic needle since a suture is "inwardly compressed" inside an aperture (Figure 7, col. 10, lines 22-26) or "swaged" to secure the material within the needle aperture, causing less trauma.
- 8. The applicant also argues that Munoz does not show a tubular needle. The examiner disagrees. The examiner acknowledges that one of the definitions of "tube" in The American Heritage Dictionary of the English Language on page 1379 is a "hollow cylinder that conveys a fluid or functions as a passage." Even so, Munoz still reads on this limitation since "hollow" can be interpreted as "having a space or cavity inside" which would be the suture hole **62** in Figure 6. Also the examiner realizes that the

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disclosure states "needle blanks 12 have a generally rectangular or 'beam' crosssection," but Munoz is referring to Figure 4, a different embodiment other than the one referred to by the examiner (of Figure 6) which shows a cylindrically-shaped needle.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MICHAEL J. HAYES SUPERVISORY PATENT EXAMINER

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